

Failure to require labeling would impose cost, confusion and chaos on the provider community. The FDA has both the legal authority and legal duty to establish a regulation requiring labeling of DEHP-containing medical devices. In addition to establishing a regulation on DEHP device labeling, the FDA should clarify in any guidance that enforcement action may be taken against inadequately labeled devices that contain DEHP. Device labeling should also reflect the reality of aggregate exposures of patients to phthalates from multiple sources, both medical and non-medical.

1) LABELING OF MEDICAL DEVICES CONTAINING DEHP IS NECESSARY AS A MATTER OF SOUND HEALTH CARE POLICY.

- a) The FDA is instructing providers to take action to protect certain patients from DEHP exposure.

In its September 2001 Safety Assessment of DEHP released from PVC Medical Devices, the FDA identified a potential hazard to certain populations. As a result of that assessment, the agency has gone forward to acknowledge that, based on animal testing, concerns about potential human effects of DEHP are significant enough that health care providers should modify their behavior to reduce the exposure of certain patient populations. For example, the *Public Health Notification* of July 12, 2002, directed to health care professionals by the FDA's Center for Devices and Radiological Health, states that providers should consider using alternative products or procedures when conducting treatments involving the relevant devices and populations:

For some of the above procedures, PVC devices that do not contain DEHP can be substituted, or devices made of other materials (such as ethylene vinyl acetate (EVA), silicone, polyethylene or polyurethane) can be used, if available. If PVC devices containing DEHP must be used, you may be able to minimize exposure to DEHP by, for example, using the freshest possible blood products stored at the lowest possible temperature, or by using heparin-coated ECMO circuits.

We recommend considering such alternatives when these high-risk procedures are to be performed on male neonates, pregnant women who are carrying male fetuses, and peripubertal males.

The draft guidance to industry and the FDA acknowledges the limits to current data, but reinforces the need for action:

Although the toxic and carcinogenic effects of DEHP have been demonstrated in laboratory animals, there are no human studies that show such effects. **What we do know is that there are certain invasive medical procedures during which exposure to DEHP could exceed the levels that are not expected to cause any adverse health effects in patients.**

.... FDA is focusing attention on the small subset of medical devices where PVC containing DEHP may come in contact with the tissue of a sensitive patient population in

a manner and for a period of time that may raise concerns about the aggregate exposure to DEHP. We believe that many devices used in Neonatal Intensive Care Units (NICUs) meet this criteria and should be a primary focus.

... the risks from DEHP-containing devices relate to: (1) the aggregate exposure and (2) the sensitivity of the exposed patient population. While devices used in neonates deserve particular attention, there may be other patient subgroups where DEHP exposure may be an issue.¹

... we recommend that you consider the feasibility of replacing PVC containing DEHP with either alternative materials or plasticizers, or using coatings that may minimize patient exposure to DEHP. Manufacturers should consider "minimizing patient exposure to DEHP" as a design requirement in their design control procedures....

b) The FDA does not propose requiring labeling of medical devices containing DEHP.

Despite the concerns described above, and the suggestions that both manufacturers and providers modify their practices to reduce patient exposure to DEHP, the draft guidance tells manufacturers that the FDA recommends, but does not require, product labeling:

...we recommend that you clearly indicate through user labeling that your device contains DEHP. **Although, at this time, FDA believes there is insufficient information to justify requiring device manufacturers to disclose the presence of this chemical in the device's labeling, there is considerable interest among some consumers and practitioners in mitigating any risks that exposure to DEHP may present.** Disclosure can assist healthcare professionals in making informed decisions regarding an individual patient's exposure to DEHP. [emphasis added]

¹ The draft guidance goes on to list devices that may be of concern. The following types of medical devices may contain PVC components, e.g., tubing or fluid containers, that could contain the chemical DEHP and expose sensitive patient populations:

Intravascular (IV) tubing and catheters/cannulae used in:

- * IV administration
- * dialysis
- * extracorporeal membrane oxygenation (ECMO)
- * cardio-pulmonary bypass (CPB) procedures.

Bags used to store and transport:

- * enteral nutrition formulae
- * total parenteral nutrition formulac.

Tubing used in enteral nutrition:

- * nasogastric tubes
- * gastrostomy tubes
- * nasojejunal tubes

To the health care community, this statement in the proposed guidance is a source of confusion and consternation. On the one hand, the agency has declared that the problem is serious enough to merit a change in provider behavior. On the other hand, the agency proposes to leave labeling as just a voluntary matter for the manufacturers. As we will discuss below, in addition to confusion, this approach is a likely source of cost and chaos for health care systems. It is also inconsistent with the FDA's statutory mandates.

- c) Provider responsiveness to the FDA notification is dependent upon providers' ability to identify DEHP containing products at the point of delivery of services, which necessitates multiple levels of labeling.

In order to effectively apply the FDA recommendation to reduce patient exposure, nurses and physicians must be able to readily distinguish a DEHP-containing device at the point of delivery of medical services from one that does not contain DEHP. Although some institutions are accelerating their shift to non-DEHP devices, it should be anticipated that for a variety of reasons, a typical health care institution may have some of both types for the foreseeable future. Because many of these devices are very similar in appearance, the only reliable method of distinguishing them throughout the institutional handling of the devices would be through multiple layers of labeling. The evidence supports several types of label requirements related to these products that are prominently and legibly displayed in conformance with section 502(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(c)):

- i) Statements on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper, "This product contains DEHP."
- ii) Labels directly on the devices, where possible, "This product contains DEHP."
- iii) A statement in the precautions section of the product insert that states that "This product contains and leaches DEHP, which has been shown in animal testing to harm the reproductive system of developing males. The Food and Drug Administration recommends that when used with neonates, women of childbearing age, pre-pubertal males, it is preferable to use a device with alternative materials where such devices are available. When considering the usage of this device, providers should recognize that patients may be exposed to phthalates from other medical and non-medical sources, which may result in additive exposure and toxicity."

For the delivery of enteral nutrition, the precaution should extend to all adults and children. If a device holds or may hold lipid containing substances, such as nutritional products or blood, then the precaution should also contain indications against warming of the products (since studies have shown that lipid products leach more DEHP when heated).

Finally, for devices where it is applicable, the precaution should also state, as was set forth in the FDA's public health notification: "The amount of DEHP that will leach out depends on the temperature, the lipid content of the liquid, and the duration of contact with the plastic."

- iv) Clarification by manufacturers and distributors in all sales materials, such as device catalogues and websites, as to whether devices being sold contain DEHP.

We are pleased to report that Health Care Without Harm members have encouraged significant progress with regard to the fourth point. Some of the major Group Purchasing Organizations have agreed to label devices in their catalogues:

- * Novation has signaled their intention to label DEHP-containing and PVC medical products in its catalogues so customers can seek more environmentally preferable alternatives.
- * Consorta will ask its shareholders for permission to label DEHP-containing and PVC products in catalogues.
- * Broadlane indicates in its online catalogue and contract implementation packages which products are free from chlorine, DEHP, latex, mercury and PVC.
- * Premier lists alternatives to DEHP and PVC-containing products in the member portion of their website.

Together these GPO's represent over \$30 billion in medical purchasing power.

However, despite the identification of DEHP products in some catalogues, this GPO initiative is far from adequate to effectively apply the FDA's recommendation across the marketplace, even for providers or health care systems that purchase through these GPO's. Labeling of devices in the catalogues does not ensure that front line providers will be notified of the hazards and be able to distinguish among devices used in their institutions. Only complete information in product inserts, combined with direct product and packaging labeling, can allow providers to effectively implement the FDA's recommendations.

- d) Manufacturers will not universally label DEHP containing devices in the absence of an FDA requirement.

Can the market demands of health care providers for properly labeled medical devices lead to proper labeling? The FDA has already considered and rejected this argument in another context. The agency looked into the possibility of a voluntary guidance for labeling of latex medical devices, an issue which arguably was even more well known to the market and which posed even more immediate risks of liability on both manufacturers and providers. Yet, the FDA concluded that leaving the issue to voluntary efforts, or to

the market, would not lead to consistent, reliable labeling.

“FDA could have issued [a] guidance [and encouraged voluntary labeling but] [w]ithout the final regulation, manufacturers may not provide any information at all.... **FDA’s own experience indicate[s] that some manufacturers never voluntarily revise their labeling.**” *Amended Economic Impact Analysis of Final Rule Requiring Use of Labeling on Natural Rubber Containing Devices*, 63 FR 29552 (1998). (emphasis added)

As will be discussed further below, current manufacturer practice on labeling of DEHP in medical devices is consistent with that FDA observation in the latex context. Without clear rules and enforcement, some manufacturers can and will choose not to label, since lack of information on hazard may cause some purchasers to buy or use such a product over similar items with proper information on DEHP. Thus, in the absence of required labeling, both economic theory and marketplace experience predict that manufacturers will compete by minimizing disclosure or availability of this detrimental information.

In its latex analysis, the FDA went on to provide additional justification:

Even if it could be assumed that all manufacturers would voluntarily provide some labeling information about the presence of natural rubber, such information is likely to be presented in a variety of ways that may confuse consumers and limit the effectiveness of the natural rubber statement. FDA believes that the provision of consistent, accurate information to consumers is critical. FDA believes that this regulation, which provides accurate, consistent information in a standardized manner, will assure that the safety information is communicated effectively to the public.

Under the provisions of the final rule, FDA estimates that most devices covered under the rule will bear the required natural rubber statement on two or three levels of labeling. FDA considered requiring labeling statements on only one level of labeling. This alternative was rejected because of the importance of the information contained in the required labeling statements. Users may not have the necessary opportunity to read the statement if it is included only on some levels of labeling. For some products, especially those with multiple users, some labeling may be discarded prior to use by subsequent consumers. The inclusion of the statement on each level of labeling increases the likelihood that consumers will be aware of the risks posed by the natural rubber in the product.

With latex, the population of potentially latex-allergic people was being protected by the labeling rule. In the case of DEHP devices, the populations at risk include pre-pubertal males, pregnant women, and women of child bearing age. As with latex, an earnest FDA effort to reduce vulnerable population exposures necessitates consistent, predictable labeling on multiple levels.

We are aware, as is the FDA, that latex and DEHP are different. Latex exposures have had observed impacts in humans since reactions are often acute, occurring immediately or shortly after an exposure. In contrast, DEHP exposures in developing boys have not been observed to have adverse impacts on reproductive tract development. However, for

DEHP; the question has never been studied. The long latency period between developmental exposures and the potential for evidence of adverse impacts makes this a particularly difficult impact to observe. As a result, to the extent that boys are injured from early exposures to DEHP, the impacts in individual cases may not be easily traceable to the early DEHP exposures.

Delayed impacts from DEHP exposure are no less important than immediate impacts - just harder to study and document. The FDA has an obligation to warn about all human health impacts whether immediate or delayed, and whether observed in humans or anticipated due to animal testing.

The practical logic of latex labeling is applicable to DEHP. In both instances, voluntary manufacturer labeling means absent, poor or inconsistent labeling on many products where providers and consumers have a clear need to know.

- e) Failure to require labeling would impose cost, confusion and chaos on the provider community.

If the FDA chooses not to require labeling, and an environment of no or inconsistent labeling is allowed to persist, the agency will avoid small costs to the manufacturers, but impose much greater cost, confusion and chaos on the health care community.

- Cost. Some providers may try to reduce DEHP exposures by labeling products or otherwise marking devices on the shelves, or by contacting manufacturers to ascertain DEHP content of products. Any such actions would require that health care institutions assign and train multiple personnel to complete this work. This would be a highly costly prospect for thousands of medical facilities. By contrast, the cost of labeling is most easily borne by the manufacturers, before DEHP containing products leave the factory's doors.
- Confusion. As noted above, if labeling is not required, providers would be receiving mixed messages from the FDA. If the issue is important enough as a potential public health issue to *recommend against exposure* under certain circumstances, as determined by the FDA safety assessment and public health notification, why isn't it important enough to provide the information needed to implement the recommendation?
- Chaos. It is realistic to expect that, given a lack of federal action on this issue, DEHP will become a growing issue of state and judicial intervention. Opportunities remain for various states to adopt regulations on labeling, or even DEHP product bans. In addition, litigation in the fields of products liability and consumer protection is a realistic possibility. Health care risk managers and legal departments are also on alert to avoid mishandling this issue in the delivery of medical care.

2) LABELING OF MEDICAL DEVICES CONTAINING DEHP IS LEGALLY NECESSARY AND APPROPRIATE UNDER FDA AUTHORITY, REGULATIONS, AND GUIDANCE.

- a) FDA has broad authority to require labeling through regulation and/or enforcement.

By its enabling statutes, the FDA has the authority and duty to establish labeling regulations, and to take enforcement action against misbranded devices. The basic authority on labeling comes from 21 USC 352, which defines the circumstances in which drugs and devices may be considered to be misbranded. This includes both the failure to provide adequate directions for use, and warnings where “use by children may be dangerous to health,” paragraph (f), and where the label is “misleading in any particular.” “Misleading” is further defined by 21 USC 321 (n):

(n) ...in determining whether the labelling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested ...but also the extent to which the labelling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles to... under such conditions of use as are customary or usual.

The findings of the 2001 FDA Safety Assessment on DEHP suggest that it may be harmful to the health of highly exposed children, and that there may be consequences from some of the uses that are customary or usual in health care settings. As we will discuss further below, we believe that even without issuing a new regulation or guidance, we believe that the FDA could presently take enforcement action against some manufacturers based on current labelling practices.

In addition, the FDA has additional authority to establish rules restricting the use of devices, including detailed, quantitative labelling of product content. The authority of the FDA to restrict the use of devices upon certain conditions also allows another clear avenue for FDA labeling of the devices. 21 U.S.C. 360j(e) provides:

- (1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use:
- (A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or
 - (B) upon such other conditions as the Secretary may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. [emphasis added]**

The enforcement of labeling of the quantity of product components of devices is described under 21 USC 352(r):

...in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing.

- b) Contrary to the draft guideline, general FDA regulations and guidelines on labeling already appear to require precautions for DEHP exposures.
 - i) The Medical Device labeling guidance (Blue Book Memorandum) implies a need for Precautions regarding DEHP.

The FDA's Blue Book Memorandum, which provides guidance on medical device labeling in general, already contains language that should be understood to require some labeling of medical devices regarding DEHP. The guidance includes the following provisions regarding Special Patient Populations:

Limitations on the usage of a device may be necessary for various reasons including lack of long-term safety and effectiveness data, lack of safety and effectiveness data for specific patient populations (e.g., pregnant women), growth processes still occurring in the body, and anatomical or physiological limitations on the effectiveness of the device.

If the safety and effectiveness of the device for use in specific patient populations have not been established on the basis of valid scientific evidence, the "Indications for Use" section shall specifically identify the persons for whose use the device is indicated and the "Precautions" section shall include the following statement:

"Safety and effectiveness in (e.g., pregnant women, children under the age of ..., etc.) have not been established."

If use of the device in a certain patient population is associated with a specific hazard, the hazard shall be described in the "Precautions" section or, if appropriate, the hazard shall be stated in the "Warnings" or "Contraindications" section and the "Precautions" section of the labeling shall refer to it, e.g., "See 'Warnings' section for information on....." [emphasis added]

On the present topic of DEHP in medical devices, there is a specific population at risk according to FDA's own analysis. If the agency believes that this guidance does not apply to this situation, much more extensive justification would seem to be needed. Otherwise, this guidance appears to provide a standing requirement for inclusion of precautionary language on DEHP in medical devices.

- ii) Where DEHP medical devices contain and are regulated as drugs, the duty to disclose DEHP hazards under FDA rules is even clearer.

The FDA's general requirements for labeling of drugs contains clear cut requirements for reporting of the existence of animal studies that indicate fertility hazards:

(f) Precautions. Under this section heading, the labeling shall contain the following subsections as appropriate for the drug:

(5) Carcinogenesis, mutagenesis, impairment of fertility. This subsection of the labeling shall state whether long-term studies in animals have been performed to evaluate carcinogenic potential and, if so, the species and results. If reproduction studies or other data in animals reveal a problem or potential problem concerning mutagenesis or **impairment of fertility in either males or females, the information shall be described. Any precautionary statement on these topics shall include practical, relevant advice to the physician on the significance of these animal findings.** If there is evidence from human data that the drug may be carcinogenic or mutagenic or that it impairs fertility, this information shall be included under the "Warnings" section of the labeling. 21 C.F.R. § 201.57(f)(5) (1993). [emphasis added]

In promulgating this rule on drug labeling, FDA explained that:

"This information may be of value to physicians in deciding whether to prescribe a particular drug for an indication, when animal data demonstrate a relationship between the use of the drug and carcinogenesis, mutagenesis, or impairment of fertility and no comparable human data exist, and when equally effective alternative drugs that do not present a risk are available." 44 Fed. Reg. 37,434, 37,450 (1979).

These regulations appear to very clearly require manufacturers that market drugs in DEHP leachable devices, or whose devices are otherwise regulated as drugs, to include specific discussion of DEHP in the precautions section of warning inserts. Presumably, it was not the intent of the FDA to alter such a requirement in its proposed DEHP guidance. However, the agency should clarify how this precaution requirement applies, both to devices that are co-packaged with drugs, and for the sake of effective and consistent policies, to devices which otherwise may leach DEHP in the course of drug administration, or in other medical contexts and uses.

- c) Failure to require labeling in the current circumstance would be arbitrary and capricious.

Health Care Without Harm has previously filed a petition for labeling of DEHP containing medical devices (June 14, 1999) and, after FDA issuance of a safety assessment and rejection of the petition in September 2001, a petition for reconsideration on October 4, 2001.

We believe that the findings of the FDA Safety Assessment, combined with the public health notification, demonstrate that the agency has found that DEHP exposures may pose substantial risks to certain populations. As a result, we believe that the agency now has a legal obligation to require labeling of DEHP medical devices.

Indeed, in the agency's letter of denial of the HCWH petition², the agency stated that:

² Letter from Linda S. Kahan, Deputy Director, Center for Devices and Radiological Health, to Sanford Lewis, Attorney for Health Care Without Harm, Sept. 5, 2001.

“we believe the evidence provided does not support your request that FDA require all PVC devices to include labeling that would warn users of the potential for DEHP leaching and warn of potential adverse health effects from DEHP... However, based on the results of the safety assessment, we recognize that risk reduction strategies may be necessary for some medical procedures that employ PVC devices, and new labeling for selected devices is one possible regulatory option.” [emphasis in original]

Thus, the FDA had, in its response, implied that labeling of some DEHP devices was under consideration. With the issuance of the draft guidance, the agency has proposed that not even *some* devices would be required to be labeled.

Given the agency’s conclusions that risk reduction is necessary, the logistics of device identification which is required to allow effective decision making at the point of use by health care providers, the current failures of manufacturers to label DEHP-containing devices adequately and consistently, and the agency’s own recognition (in the latex context) that voluntary labeling means inconsistent and sometimes absent labeling, we believe that it would be unlawful for the FDA to fail to require labeling of devices. Such a decision would be irrational, unsupported by the relevant facts and factors, counter to the evidence, and inconsistent with the agency’s statutory duties.

It is worth noting the contrast between this case and the 1996 court decision of Henley v. FDA, 77 F 3rd 616 (2d Cir. 1996). In that case, Henley, an attorney for a women’s health organization, had petitioned the FDA to label oral contraceptives to include an animal carcinogen warning. There were animal tests showing carcinogenesis. But the FDA, in denying the petition, pointed to the existence of human epidemiological studies which exonerated the estrogen compounds:

"Numerous epidemiological studies have been performed on the incidence of breast, endometrial, ovarian, and cervical cancer in women using oral contraceptives. The overwhelming evidence in the literature suggests that use of oral contraceptives is [*619] not associated with an increase in the risk of developing breast cancer, [**6] regardless of the age and parity of first use or with most of the marketed brands and doses. The Cancer and Steroid Hormone (CASH) study also showed no latent effect on the risk of breast cancer for at least a decade following long-term use. A few studies have shown a slightly increased relative risk of developing breast cancer, although the methodology of these studies, which included differences in examination of users and nonusers and differences in age at start of use, has been questioned."

Based on the existence of the exonerating human studies, the FDA declined to require product labels to state the existence of animal studies raising concerns of carcinogenicity. The court sustained the agency’s decision on the basis of those human studies, which provided a rational basis for the agency’s decision that product labels would be adequate, and not misleading, without mention of those animal studies.

By contrast, in the present matter the agency has gone on the record repeatedly implying that the animal studies appear to be relevant to human exposures, and to prediction of human impacts. In the Safety Assessment, for instance, the agency stated, "There is no mechanistic reason to believe that reproductive effects seen in DEHP-exposed rodents are not relevant for humans." Here, there are no human exculpatory studies, and the agency has indicated that the appropriate health response is to reduce exposures of the vulnerable populations. Without labeling, such a response will be ineffective, and thus, without requiring labeling, the FDA's decision to not label would be counter to the evidence before the agency. Also, as will be discussed below, product packaging that fails to mention DEHP, where the products in question may be used upon the vulnerable populations, would be misleading, and therefore would constitute misbranded products – a market circumstance that the FDA is obliged to prevent.

Since all medical devices may at times be used on individuals in the vulnerable populations, and since providers and the FDA must, as discussed below, consider aggregate exposures of these patients from multiple medical and non-medical sources, we believe the FDA's legal duty is to label all medical devices that contain DEHP.

d) Regardless of whether the FDA establishes a regulation, the agency must take enforcement action against misbranded DEHP medical devices, and must not dispense with its authority to take such enforcement.

Current manufacturer practice shows that FDA **requirements** and **enforcement** are necessary to protect the populations at risk. As discussed above, labels that reach end users should consist of:

- i) Labeling of products and packaging that is readily apparent to health care providers at the point of delivery of services to distinguish whether a product contains DEHP; and
- ii) Precautions indicating that animal studies have indicated potential hazards to male reproductive systems and that health care providers should avoid exposure of certain populations where there are alternative devices available.

The FDA should conduct a thorough examination of product labeling for DEHP. Based on our limited examination of the labels of a few products, we were unable to determine whether some products examined contained DEHP. However, our limited review amplified the concern that neither of the above conditions for proper labeling seem to be met:

- i) There are currently devices on the market which we believe to contain both PVC and DEHP but which are not labeled as to the presence of either.
- ii) There are devices being sold that make references that may indicate that they are DEHP-containing devices -- but which are vague enough that the user would not be able to tell:

- “The flexible plastic container is fabricated from a specially formulated polyvinyl chloride... Solutions inside the plastic container also can leach out certain of its chemical components in very small amounts before the expiration period is attained. However, the safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers.” (Source: Abbott Dextrose, USP container)

- “Solutions in contact with the plastic container may leach out certain chemical components of the plastic in very small amounts, however, biological testing was supportive of the safety of the plastic container materials.” (Source: Abbott sodium chloride injection USP flexible plastic container)

iii) There are devices that contain precautions which may be misleading in light of the existence of animal studies on DEHP:

- Precautions: “Carcinogenesis, Mutagenesis, Impairment of Fertility: “Studies with dextrose injection, USP, have not been performed to evaluate carcinogenic, mutagenic potential or effects on fertility.” (Source: Abbott Dextrose injection USP, flexible plastic container) (Note that if this is a device that contains DEHP, which it may be, this seems particularly problematic. The materials leached from the device seem to require affirmative statement of fertility impacts in animal tests, even though other materials in the bag may not.)

iv) Other medical devices potentially containing DEHP have ambiguous statements in the precautions section of warning inserts that may be relevant to the use of DEHP in the device, such as where the devices state, as per FDA’s guidance, that the device has not been proven safe for pregnant women or children. These statements taken alone are misleading, where there is also known evidence from animal studies which the FDA has deemed relevant to humans and which the manufacturer declines to mention.

We strongly recommend that the FDA promulgate a regulation requiring labeling of DEHP medical devices. However, even in the event that the agency declines to establish a regulation, the guidance should make it clear that individual manufacturers may be subject to enforcement action for misbranding under existing law for failure to label DEHP-containing devices properly.

In contrast, the current guidance could be construed by manufacturers to state that they will not be considered in violation of the statutory prohibition against misbranding for failure to label for DEHP, or even the current drug labeling rule or medical device labeling guidance. Therefore, instead, the DEHP guidance should:

- Explain issues of DEHP labeling duties in the context of the existing drug labeling rule and medical device labeling guideline;

- Indicate that the agency will commence enforcement investigations on DEHP labeling within three months of the completion of the guideline;
- List a set of scenarios under which manufacturers could be subject to enforcement for misbranding.

In addition, we urge the agency to investigate current manufacturer labeling practices and to take enforcement action where manufacturers are engaged in misbranding.

3) THE GUIDANCE ERRONEOUSLY OMITTS IMPORTANT PATIENT POPULATIONS.

The draft guidance mentions neonates as a sensitive patient population, and acknowledges that there may be other patient subgroups where DEHP exposure may be an issue. It does not, however, explicitly identify those other subgroups for a provider intending to follow the recommendations. The guidance should make it clear, as well, that male neonates, women who are pregnant with a male fetus, and all boys until the age of puberty, are among the sensitive subgroups where DEHP exposure may be an issue. These were subgroups previously indicated in the FDA's public health notification; to omit them here would send inconsistent messages to manufacturers and the FDA compared with that sent to the health care community. In addition, we believe the groups of concern should be expanded to women of childbearing age, since it is often not immediately ascertained whether such a woman is pregnant, and the earliest stages of pregnancy may be the most vulnerable time for exposure.

4) THE GUIDANCE FAILS TO REFLECT ISSUES OF AGGREGATE EXPOSURE.

a) Aggregate exposures to phthalates are relevant to providers, manufacturers and the FDA.

The draft guidance and the FDA public health notification about DEHP give no indication to manufacturers or providers that people are also exposed to DEHP and other phthalates from numerous sources other than medical devices. Biomonitoring studies conducted by the CDC and other investigators conclusively demonstrate that the general population is regularly exposed to DEHP and other phthalates. See Attachment 2. Moreover, animal studies demonstrate that some members of the phthalate family of chemicals have similar toxicological impacts on the developing male reproductive tract. In fact, CDC biomonitoring data in the general population found that women of reproductive age appeared to have some of the highest exposures to di-butyl phthalate (DBP). DBP is a phthalate which has been observed in animal testing to have the same impacts on the development of male reproductive tract as seen with DEHP.

As a result of these observations, it follows that DEHP exposures from medical devices must not be viewed as isolated and single exposures, but rather must be viewed as contributing to aggregate exposures to phthalates with similar toxicological properties.

This conclusion is of obvious relevance to practitioners contemplating the use of a DEHP-containing medical device, particularly in a patient from a sensitive subgroup.

b) Aggregate exposures of vulnerable populations necessitate universal labeling of medical devices that contain DEHP.

Given the reality of aggregate phthalate exposures from multiple sources, even small doses of DEHP coming from various medical devices may in the aggregate be harmful to sensitive populations exposed to an array of medical procedures. Also, since virtually any medical device that contains and leaches DEHP may at times be used with sensitive populations, it is necessary for the FDA to require labeling for all medical devices that contain and leach DEHP. Labeling of all such devices is the only way to allow providers to systematically reduce the exposures of the sensitive populations identified by the agency's safety assessment and public health notification.

Respectfully submitted,

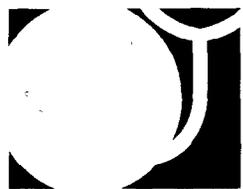


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Attachment 1: HCWH Member List

Attachment 2: Aggregate Exposure to Phthalates in Humans, HCWH report

Health Care



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As of November 25, 2002

394 Organizations in 44 Countries

Academic/Research (11)

Center for a Livable Future, Johns Hopkins University School of Hygiene & Public Health, Baltimore MD
Center for Ethics and Toxics, Gualala CA
Center for the Biology of Natural Systems, Flushing NY
Columbia University, College of Physicians and Surgeons, Rosenthal Center, New York NY
Department of Environmental Health, Boston University School of Public Health, Boston MA
Florida Atlantic University College of Nursing, Boca Raton FL
Great Lakes Center for Occupational & Environmental Safety & Health, Chicago IL
The Green Health Center, University of Nebraska Medical Center, Omaha NE
Institute of Environmental Medicine and Hospital Epidemiology, University Hospital Freiburg, Freiburg Germany
Mt. Sinai School of Medicine, New York NY
University of Illinois School of Public Health, Chicago IL

Environmental Consulting (4)

ETA Umweltmanagement, Vienna Austria
European Institute for Transfer of Technology, Information Management and Communication, Freiburg Germany
Lightning Environmental Systems, Shrewsbury MA
Raymond Schelker Environmental Consulting, Reinach Switzerland

Environmental Health (11)

Center for Environmental Health, Oakland CA
Commonweal, Bolinas CA
Ecological Health Organization, Inc., Hebron, CT
The Environmental Health Fund, Boston MA
Jennifer Altman Foundation, Bolinas CA
Judith Helfand Productions, New York NY
The Network for Women's and Children's Environmental Health, South Bend IN
New York Coalition for Occupational Safety and Health, NY
The Nightingale Institute for Health & the Environment, Essex Jct. VT
Oregon Center for Environmental Health, Portland OR
Second Look, Worcester MA

Agriculture (3)

Farm-Verified Organic, Medina ND
Institute for Agriculture & Trade Policy, Minneapolis MN
Kirschenmann Family Farms, Windsor ND

Health Care Professionals (38)

Alabama State Nurses Association, Montgomery, AL
Alaska Nurses Association, Anchorage AK
Ambulatory Pediatric Association, McLean VA
American College of Nurse-Midwives, Washington DC
American Nurses Association, Washington DC
American Public Health Association, Washington DC
Association of Physicians and Medical Workers for Social Responsibility, Nairobi, Kenya
Canadian Association of Physicians for the Environment, Klemburg, ON Canada
Committee of Interns and Residents, New York NY
Connecticut Nurses Association, Meriden CT
Delaware Nurses Association, Newark DE
Greater Boston Physicians for Social Responsibility, Boston MA
Heal With Nature, Avon, CT
International Council of Nurses, Geneva Switzerland
International Society for Doctors for the Environment (ISDE), Santa Fe Argentina and Corcelles-sur-Chavornay Switzerland
Infusion Nurses Society, Norwood MA
Maryland Nurses Association, Linthicum, MD
Massachusetts Nurses Association, Canton MA
Medact, London UK
Michigan Nurses Association, Okemos MI
Montana Nurses Association, Helena MT
New Hampshire Nurses' Association, Concord NH
New York State Nurses Association, Latham NY
North Carolina Nurses Association, Raleigh NC
Ohio Nurses Association, Columbus OH
Oregon Federation of Nurses and Health Professionals, Local 5017, AFT/AFL-CIO, Clackamas, OR
Oregon Nurses Association, Portland, OR
Texas Nurses Association, Austin, TX
Oncology Nursing Society, Washington DC
Physicians for Social Responsibility, Washington DC
Physicians for Social Responsibility - Bay Area Chapter, San Francisco CA
Physicians for Social Responsibility-Los Angeles, Santa Monica CA
Physicians for the Environment Switzerland AefU, Basel Switzerland
San Francisco Medical Society, San Francisco CA
South Carolina Nurses Association, Columbia SC
Surfer's Medical Association, San Francisco CA
Vermont State Nurses Association, Winooski VT
Washington Physicians For Social Responsibility, Seattle, WA

Health Care Institutions (114)

Beth Israel Medical Center, New York NY
Catholic Health Association, St. Louis MO
Catholic Health East, Newtown Square PA

- Bayfront Medical Center, St. Petersburg FL
- Girard Medical Center, Philadelphia PA
- Good Samaritan Medical Center, West Palm Beach FL
- Holy Cross Hospital, Fort Lauderdale FL
- Kenmore Mercy Hospital, Kenmore NY
- Mease Countryside Hospital, Safety Harbor FL
- Mease Dunedin Hospital, Dunedin FL
- Mercy Community Hospital, Havertown PA
- Mercy Fitzgerald Hospital, Darby PA
- Mercy Hospital, Buffalo NY

- Mercy Hospital , Miami FL
- Mercy Hospital, Springfield MA
- Mercy Hospital of Philadelphia, Philadelphia PA
- Mercy Hospital Portland , Portland, ME
- Mercy Medical , Daphne AL
- Mercy Providence Hospital , Pittsburgh PA
- Mercy Suburban Hospital , Philadelphia PA
- Morton Plant Hospital , Dunedin FL
- North Bay Hospital, New Port Richey FL
- Our Lady of Lourdes Medical Center , Camden NJ
- Our Lady of Victory Hospital, Lackawanna NY
- Rancocas Hospital , Willingboro NJ
- Saint Joseph's Hospital of Atlanta , Atlanta GA
- St. Anthony's Hospital, St. Petersburg FL
- St. James Mercy Hospital, Hornell NY
- St. Joseph Hospital, Cheektowaga NY
- St. Joseph's Hospital , Philadelphia PA
- St. Joseph's Hospital, Tampa FL
- St. Mary's Hospital , Athens GA
- St. Mary's Hospital , West Palm Beach FL
- St. Peter's Hospital, Albany NY
- Sisters of Charity Hospital , Buffalo NY
- South Florida Baptist, Plant City FL
- The Mercy Hospital of Pittsburgh, Pittsburgh, PA
- Catholic Healthcare West, San Francisco CA
- Bakersfield Memorial Hospital, Bakersfield CA
- California Hospital Medical Center, Los Angeles CA
- Chandler Regional Hospital, Chandler AZ
- Community Hospital of San Bernadino, San Bernadino, CA
- Dominican Hospital, Santa Cruz CA
- Glendale Memorial Hospital & Health Center, Glendale CA
- Green Hospital of Scripps Clinic, La Jolla CA
- Long Beach Community Medical Center, Long Beach CA
- Marian Medical Center, Santa Maria CA
- Mark Twain St. Joseph's Hospital, San Andreas CA
- Mercy American River Hospital/Mercy San Juan Hospital Carmichael CA
- Mercy General Hospital, Sacramento CA
- Mercy Hospital, Bakersfield CA
- Mercy Hospital and Health Services, Merced CA
- Mercy Hospital of Folsom, Folsom CA
- Mercy Medical Center Mt. Shasta, Mt. Shasta CA
- Mercy Medical Center Redding, Redding CA
- Mercy Southwest Hospital, Bakersfield CA
- Mercy Westside Hospital, Taft CA
- Methodist Hospital of Sacramento, Sacramento CA
- Northridge Hospital Medical Center, Northridge CA
- Northridge Hospital Medical Center, Van Nuys CA
- Oak Valley Hospital District, Oakdale CA
- O'Connor Hospital, San Jose CA
- Robert F. Kennedy Medical Center, Hawthorne CA
- Saint Francis Memorial Hospital, San Francisco CA
- Saint Louise Hospital, Morgan Hill CA
- San Gabriel Valley Medica Center, San Gabriel CA
- Scripps Health, San Diego CA
- Sequoia Hospital, Redwood City CA
- Seton Medical Center Coastsides, Moss Beach CA
- Seton Medical Center, Daly City CA
- Sierra Nevada Memorial Hospital, Grass Valley CA
- St. Bernardine Medical Center, San Bernardino CA
- St. Dominic's Hospital, Manteca CA
- St. Elizabeth Community Hospital, Red Bluff CA
- St. Francis Medical Center, Lynwood CA
- St. Francis Medical Center, Santa Barbara CA
- St. John's Pleasant Valley Hospital, Camarillo CA
- St. John's Regional Medical Center, Oxnard CA
- St. Joseph's Hospital & Med. Center, Phoenix AZ
- St. Joseph's Medical Center, Stockton CA
- St. Mary Medical Center, Long Beach CA

- St. Mary's Medical Center, San Francisco CA
- St. Rose Dominican Hospital, Henderson NV
- St. Vincent Medical Center, Los Angeles CA
- Woodland Healthcare, Woodland CA

Catholic Health Initiatives, Denver, CO
 Centro Clinico Colle Cesarano, Roma Italy
 Day Hospital Institute for Development & Rehabilitation, Cairo, Egypt
 Fletcher Allen Health Care, Burlington VT
 Gentofte County Hospital, Gentofte, Denmark
 Hackensack University Medical Center, Hackensack, NJ
 Holy Redeemer Health System, Huntingdon Valley PA
 Huddinge University Hospital, Stockholm, Sweden
 Kaiser Permanente, Oakland, CA
 The Hospital Services of Aarhus County, Aarhus, Denmark

- Randers Central Hospital
- Grenaa Central Hospital
- Odder Central Hospital
- Silkeborg Central Hospital
- Aarhus University Hospital
- Riiskov Psykiatric Hospital
- Skejby Hospital
- Aarhus County Hospital
- Aarhus Kommunehospital

Inova Alexandria Hospital, Alexandria VA
 Inova Fairfax Hospital, Falls Church VA
 Inova Fairfax Hospital for Children, Falls Church VA
 Inova Fair Oaks Hospital, Fairfax VA
 Inova Hospital Mount Vernon, Alexandria VA
 National Dental Hospital-Nepal, Kathmandu, Nepal
 New England Medical Center, Boston MA
 Scripps Health, San Diego CA
 Swiss Hospital Association
 Vienna Hospital Association

Health Impacted (20)

Breast Cancer Action, San Francisco CA
 The Breast Cancer Fund, San Francisco CA
 Chemical Impact Project, Kentfield CA
 DES Cancer Network, Washington DC
 Endometriosis Association, Milwaukie WI
 Endometriose Foreningen, Varde, Denmark
 Learning Disabilities Association, Pittsburgh PA
 Living/Dying Project, Fairfax CA
 Massachusetts Assn. for the Chemically Injured, Inc. Arlington MA
 Massachusetts Breast Cancer Coalition, Waltham MA
 MCS: Health & Environment, Evanston IL
 Multiple Chemical Sensitivities Task Force of New Mexico, Santa Fe NM
 National Brain Tumor Foundation, Oakland CA
 Ohio Network for the Chemically Injured, Parma OH
 Trinity Services, Inc., Joliet, IL
 Vietnam Veterans of America- Michigan Chapter, Saline MI
 White Lung Association, Baltimore MD
 Women's Cancer Resource Center, Berkeley CA
 Women's Cancer Resource Center, Minneapolis MN
 Women's Community Cancer Project, Cambridge MA

Indigenous Peoples & Environmental Justice Groups (15)

Arab Community Center for Economic and Social Services, Dearborn MI
 American Indian Health, Dearborn MI
 Chicago Jobs With Justice, Chicago IL
 Community Coalition for Environmental Justice, Seattle WA
 Connecticut Coalition for Environmental Justice, Hartford CT
 Detroiters Working for Environmental Justice, Detroit MI
 Greater Cleveland Coalition for a Clean Environment, Cleveland OH
 Human Action Community Organization, Harvey IL
 Indigenous Environmental Network, Bemidji MN
 Jews United For Justice, Washington DC
 Lawrence Environmental Justice Council, Lawrence MA
 Mohave Elders of the Colorado River Indian Tribes, Parker AZ

People United for a Better Oakland (PUEBLO), Oakland CA
Reduce Recidivism by Industrial Development, Inc., Chicago IL
South Bronx Clean Air Coalition, Bronx NY

International Environmental Groups (76)

Agenzia Lucchese Per L'Energia Ed Il Recupero Delle Risorse (ALERR), Lucca Italy
AGENDA, Dar es Salaam, Tanzania
Alihuen, Santa Rosa Argentina
Alternative Information and Development Centre, Mowbray South Africa
La Asociación Civil Crecer, Santa Fe Argentina
Asociación Vecinal Moronense, Buenos Aires, Argentina
Baikal Environmental Wave, Irkutsk, Russia
Belgian Platform Environment and Health, Nieuwerkerken Waas, The Netherlands
Caritas Manila, Manila, Philippines
Cebu Environmental Initiatives for Development Center, Inc., Cebu City, Philippines
Canadian Coalition for Green Health Care, Toronto, ON
Centre national d'information indépendante sur les déchets (CNIID), Paris France
Centre for Environmental Education, New Delhi, India
Centro de Derecho Ambiental del Noreste de Mexico, Chihuahua Mexico
Centro de Derecho Ambiental e Integración Económica del sur A.C. (DASSUR), Xalapa Mexico
Centro Ecologista Renacer, Santa Fe, Argentina
Centro de Educación Médica e Investigaciones Clínicas "Norberto Quirno", Buenos Aires, Argentina
Clean North, Sault St. Marie ON, Canada
Climate and Development Initiatives, Kampala Uganda
Communities Against Toxics, Ellesmere Port UK
Community Sanitation and Recycling Organization, Phnom Penh, Cambodia
Comite Sante Environnement, Beziers France
Committee on Vital Environmental Resources, Benin City, Nigeria
Consultores de Eficiencia en Trabajos Ambientales, San José, Costa Rica
The Consumers Association of Penang, Pulau Pinang Malaysia
Deti Zeme- Children of the Earth, Praha, Czech Republic
Direct Initiative for Social and Health Action, Calcutta India
The Ecological Council, Copenhagen, Denmark
Free Planet International, Kampala, Uganda
Friends of the Earth Society (Spoločenstvo priateľov Zeme), Kosice, Slovakia
Green Communities, Peterborough ONT Canada
Greenpeace Argentina, Buenos Aires, Argentina
Greenpeace Mediterranean, Beirut Lebanon
groundWork, Pietermaritzburg South Africa
Health, Education & Environmental Crusaders, Port Harcourt, Nigeria
Industrial Pollution Prevention Center, Hijdeu, Republic of Moldova
The Institute for Sustainable Healthcare (Institut für Nachhaltigkeit im Gesundheitswesen), Vienna Austria
The International Physicians for the Prevention of Nuclear War, Lusaka, Zambia
LIFE Youth Foundation, Bihor, Romania
Livaningo, Maputo, Mozambique
MAMA-86-Kharkov, Ukraine
Mother Earth Foundation, Enschede The Netherlands
Movimiento Antinuclear del Chubut/Sistemas Ecológicos Patagónicos, Buenos Aires, Argentina
Mumbai Med-Waste Action Group, Mumbai India
OMESC-Comité Santé Environnement, Beziers, France
Organisation for Ecologically Sustainable Waste Management, Co. Kilkenny, Ireland
Pollution Control Association of Liberia, Monrovia, Liberia
Pollution Probe, Toronto ONT
Public NGO "Maria" Volgograd, Russia
Red de Acción Sobre Plaguicidas y Alternativas en Mexico, Texcoco Mexico
Red Fronteriza de Salud y Ambiente, A.C., Sonora Mexico
RECONCILE Resources Conflict Institute, Nakuru Kenya
Réseau Sénégalais d'Information sur les Déchets, Dakar Senegal
Probiobiodiversity Conservationists, Kampala, Uganda
Sahabat Alam Malaysia-Friends of the Earth, Penang Malaysia
Save Earth Nigeria, Port Harcourt Nigeria
Save Bombay Committee, Mumbai India
Slovenia Clean Production and Right-to-Know Action, Ankaran Slovenia

Society for Awareness and Growth in Etche, Port Harcourt Nigeria
Society for Conservation and Protection of the Environment, Karachi Pakistan
Society of Jyotsna Chauhan, Andhra Pradesh, India
Society for Water and Public Health Protection, Benin City, Nigeria
Srishti, New Delhi India
Taller Ecologista, Rosario. Argentina
THANAL, Keralam India
Toronto Environmental Alliance, Toronto Canada
Toronto Bay Initiative, Toronto Canada
Uganda Convention For Development, Kampala, Uganda
Uganda Wildlife Society, Kampala, Uganda
Unidad Ecologica Salvadoreña, San Salvador El Salvador
Waste and the Environment. Rijswijk, The Netherlands
Waste Prevention Association „3R“, Krakow Poland
World Wide Fund For Nature, Lahore Pakistan
Yonge Nawe, Mbane Swaziland

Groups Working On Environmental Issues in U.S. (67)

Alaska Community Action on Toxics, Anchorage AK
Asia Pacific Environmental Exchange, Seattle WA
Berkeley Ecology Center, Berkeley, CA
Beyond Pesticides, Washington, DC
Blue Ridge Environmental Defense League, Wadesboro NC
California Communities Against Toxics, Rosamond CA
Center for Health, Environment and Justice, Falls Church VA
Children for a Safe Environment, Phoenix AZ
Citizens Environmental Coalition, Albany NY
Citizens for a Better Environment, Chicago IL
Citizens for a Better Environment, Madison, WI
Citizens for a Better Environment, Minneapolis MN
Citizens for a Healthy and Safe Environment, Colchester VT
Citizens for the Protection of Butler Township, Rankin IL
Cleanup Coalition, Baltimore MD
Earth Day Coalition, Cleveland OH
EarthSave, Louisville KY
Ecology Center, Ann Arbor MI
Environmental Association for Great Lakes Education, Duluth MN
Environmental Working Group, Washington DC
Equis, Langley WA
Essential Action, Washington DC
The Evergreen Association, Morgantown PA
Galveston-Houston Association for Smog Prevention, Houston TX
Gateway Green Alliance, St. Louis MO
Global Community Monitor, San Francisco, CA
Government Purchasing Project, Washington DC
Grass Roots Environmental Organization, Rahway NJ
Great Lakes United, Buffalo NY
Greenaction, San Francisco CA
Green Decade Coalition, Newton MA
Greenpeace, Washington DC
Hamtramck Environmental Action Team, Hamtramck MI
Institute for a Sustainable Future, Duluth MN
The Katahdin Center for Education and Research, Brunswick ME
LocalMotion, Ann Arbor MI
Lone Star Chapter of the Sierra Club, Austin TX
Maryland Public Interest Research Group (MaryPIRG), Baltimore MD
Massachusetts Public Interest Research Group (MASSPIRG), Boston MA
Mid-Michigan Environmental Action Council, E. Lansing MI
Minnesota Center for Environmental Advocacy, St. Paul MN
Multinationals Resource Center, Washington DC
National Resources Council of Maine, Augusta ME
National Wildlife Federation, Washington DC
Natural Resources Defense Council, Washington DC
New Girl Times, New York NY
NJ/NY Environmental Watch, Elizabeth NJ
North Carolina Waste Awareness & Reduction Network, Durham NC
Pennsylvania Environmental Network, Shippensburg, PA
Save Our County, East Liverpool OH
Science and Environmental Health Network, Windsor ND

Sierra Club, Washington DC
Sierra Club, California, San Mateo, CA
Sierra Club, Cascade Chapter, Bothell WA
Sierra Club, Lone Star Chapter, Austin TX
Sierra Club, Rincon Group, Tucson AZ
Sierra Club, Southeast Michigan Sierra Club, Detroit MI
Stanly Citizens Opposed to Toxic Chemical Hazards (SCOTCH), Albemarle NC
St. Louis Medical Waste Incinerator Group, St. Louis MO
Toxics Action Center, Boston MA
Toxics Action Center, West Hartford CT
United Citizens and Neighbors, Urbana IL
Vermont Public Interest Research Group, Montpelier VT
Washington Toxics Coalition, Seattle WA
West Michigan Environmental Action Council, Grand Rapids MI
Women's Voices for the Earth, Missoula MT
Work on Waste, Canton MA

Legal (4)

Bangladesh Environmental Lawyers Association, Dhaka Bangladesh
Earth Rights International, Seattle WA
Legal Environmental Assistance Foundation, Tallahassee FL
National Environmental Law Center, Boston MA

Religious (9)

California, Nevada Board of Church & Society, United Methodist Church, Santa Cruz CA
Cathedral of Saint John the Divine, New York NY
Central Conference of American Rabbis, New York NY
Episcopal Diocese of Massachusetts, Boston MA
General Board of Church & Society, United Methodist Church, Washington DC
Lafayette Avenue Presbyterian Church, New York, NY
Methodist Federation for Social Action, Mason City IL
Presbytery of New York City, New York, NY

Reconstructionist Rabbinical Association, Philadelphia PA

Student (5)

Illinois Student Environmental Network, Champaign IL
Student Environmental Action Coalition, Philadelphia PA
Students for a Healthy Hospital, Ann Arbor MI
Students for a Healthy Hospital, Eugene OR
Student Physicians for Social Responsibility, Urbana IL

Unions (3)

AFL-CIO, Washington DC
California Nurses Association, Sacramento CA
Service Employees International Union, Washington, DC

Women's Health Orgs (8)

Action for Women's Health, Albuquerque NM
Armenian Women for Health and a Healthy Environment, Yerevan Armenia
Maria, Volgograd, Russian Federation
National Women's Health Alliance, Inc., New York NY
National Women's Health Network, Moretown VT
Women's Environment and Development Organization (WEDO), New York NY
Women's Health and Environmental Network, Philadelphia PA
Women in Europe for a Common Future, Utrecht, The Netherlands

Recycling and Medical Product Redistribution (4)

Medisend, Dallas, Texas
Chicago Recycling Coalition, Chicago IL
Grass Roots Recycling Network, Athens GA
REMEDY – Recovered Medical Equipment for the Developing World, New Haven, CT